Informed consent form (ICF)

USE OF DEXMEDETOMIDINE DURING CAROTID ENDARTERECTOMY: SAFETY PROFILE, AND SATISFACTION OF THE PATIENT AND OPERATORS

version I 8th November 2020

Approved by local Ethics Committee on 10th February 2021

(Protocol n. 0031200/2021)

SANT'EUGENIO HOSPITAL

INFORMED CONSENT

LONGITUDINAL OBSERVATIONAL COHORT STUDY ON DRUGS

USE OF DEXMEDETOMIDINE DURING CAROTID ENDARTERECTOMY: SAFETY PROFILE, AND SATISFACTION OF THE PATIENT AND OPERATORS

Dear Patient,

The purpose of this informed consent is to propose your participation in a non-profit research, an observational study entitled: USE OF DEXMEDETOMIDINE DURING CAROTID ENDARTERECTOMY: SAFETY PROFILE, AND SATISFACTION OF THE PATIENT AND OPERATORS, which provides exclusively for the collection of data relating to the population of patients undergoing carotid endarterectomy. You will be able to decide, based on the information received and in absolute freedom, whether to authorize the collection and processing of your sensitive personal data (e.g. your state of health).

Study Objective

The objective of the observational epidemiological study is to evaluate the efficacy and tolerability of dexmedetomidine during carotid endarterectomy versus fentanyl and midazolam.

What does participation in the study entail

The study does not aim to modify the therapy or administer drugs different from those currently in use, nor to subject you to therapeutic or diagnostic procedures different from those foreseen for you in the context of common clinical practice for the treatment of your pathology. Specifically, in the preparation room, before the surgical procedure, you will be assigned to the dexmedetomidine group or the fentanyl and midazolam group. At that point you will be able to confirm the proposed group or

choose the other based on your preference. If you decide to participate in the Study, you will be subjected to data collection that will be carried out exclusively during routine follow-ups using dedicated data collection forms. Information will be collected regarding your clinical history, a diary of events during the surgery and finally your degree of satisfaction with the procedure.

What are the risks of participating in the study

The Study does not involve procedures other than usual clinical practice, therefore it does not present additional risks. Your participation simply allows us to collect and analyze the information and to disclose it to the scientific community in full compliance with the current legislation on the processing of personal data (Legislative Decree 196/2003 and GDPR 679/2016).

What happens if you decide not to participate in the study

You are free not to participate in the Study. In any case, you will receive all the tests and therapies provided for your pathology, without any penalty, and the Doctors will continue to follow you in any case with the necessary care.

Interruption of the study

Your participation in the study is completely voluntary and you can withdraw at any time and for any reason, possibly by communicating it to the Doctor who is following you for this Study.

The Study and this Informed Consent have been approved by the Independent Ethics Committee to which this Hospital belongs, the Committee is an independent body made up of experts in various disciplines, who work to protect and guarantee the patients involved in clinical studies.

Declaration of consent

I, the undersigned:

declare that I have received from Doctor_____

exhaustive explanations regarding my participation in the "Observational Study entitled USE OF DEXMEDETOMIDINE DURING CAROTID ENDARTERECTOMY SURGERY: SAFETY PROFILE, AND SATISFACTION OF THE PATIENT AND OPERATORS" as reported in the information sheet attached, a copy of which was delivered to me sufficiently in advance;

• that I have been able to discuss these explanations; that I have been able to ask all the questions I deemed necessary and that I have received satisfactory answers, regarding my participation in the Study;

• that I am aware that at any time and for any reason I may withdraw from the Study and still be treated with the ordinary therapies for the disease from which I suffer, without the obligation to justify the decision;

• that my participation is free, not influenced by promises of money or other benefits, nor by obligations of gratitude or friendship and/or kinship towards the Doctor who proposes the Study;

• to have been informed of my right to have free access to the documentation that concerns me relating to the Study and to the evaluation expressed by the Independent Ethics Committee;

• to authorize from now on the use and disclosure, in anonymous form, for scientific and administrative purposes only and in compliance with the current regulations on the protection of confidentiality, of the results of the Study, including the clinical data that concern me, in full compliance with the legislation in force in Italy on the protection of personal data Legislative Decree 196/2003 and GDPR 679/2016;

• to therefore freely accept to participate in the Study, having fully understood the meaning of my participation.

Date Signature of the patient

_____ _____

Date Signature of the investigator

_____ _____

Information and consent to the processing of personal data

Data controllers and related purposes

The Clinical Center UOC ANESTHESIA AND RESUSCITATION of the Sant'Eugenio Hospital Promoter of the observational Study described to you, in accordance with the responsibilities provided for by the rules of good clinical practice, will process your personal data, in particular those on health and, only to the extent that they are essential in relation to the objective of the study, in full compliance with the current legislation on the protection of personal data (Legislative Decree 196/2003 and GDPR 679/2016). To this end, the data indicated will be collected by the Experimentation Center and processed there.

We inform you that the aforementioned Data Controller, pursuant to Article 37 of GDPR 2016/679, has proceeded to identify and appoint the Data Protection Officer (also "Data Protection Officer" or "DPO"): Dr. Massimo GALLETTI

Legal basis of processing

The informed consent, freely given by you, constitutes the legal basis for the processing of your data for the purposes described in the information sheet. In the absence of signed consent, we will not be able to use your data for the conduct and analysis of the Study.

The processing of personal data relating to your health, age, sex are essential for the conduct of the study: refusal to provide them will not allow you to participate.

Special categories of personal data

Pursuant to Articles 26 and 27 of Legislative Decree 196/2003 and Articles 9 and 10 of EU Regulation no. 2016/679, you may provide the data controller with data that can be classified as "special categories of personal data", i.e. data that reveal "ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, as well as genetic data, biometric data intended to uniquely identify a natural person, data relating to the health or sexual life or sexual orientation of the person". These categories of data may be processed only with your free and explicit consent, expressed in written form at the bottom of this information.

Nature of data

The Doctor who will follow you in the study will identify you with a code: the data concerning you collected during the study, with the exception of your name, will be recorded, processed and stored together with this code, your state of health, your date of birth, your sex. Only the Doctor and the subjects authorized by law will be able to connect this code to your name.

Method of processing

The data, processed using electronic tools, will be disclosed only in a strictly anonymous form, for example through scientific publications, statistics and scientific conferences.

Exercise of rights

You may exercise the rights under art. 7 of the Privacy Code (Legislative Decree 196/2003 as well as those under articles 15 to 22 of GDPR 679/2016) e.g. access your personal data, integrate them, update them, rectify them, oppose their processing for legitimate reasons, etc. by contacting the doctor who follows you, Dr. Massimo GALLETTI, available at the telephone number 0651002345. You also have the right to submit a formal complaint to the Guarantor for the protection of personal data in the event of violation of your rights regarding the protection of privacy.

Right to information

You have the right to obtain information on the personal data concerning you, on how they will be collected, processed or, if necessary, transferred to third parties. You may interrupt your participation in the study at any time and without providing any justification. Furthermore, no further data concerning you will be collected, without prejudice to the use of any data already collected to determine, without altering them, the results of the research, unless you request that they be deleted.

Consent

I, the undersigned, in light of the information received

□ express consent □ I DO NOT express consent to the processing of my personal data including those considered as special categories of data.

□I give my consent □ I DO NOT give my consent to the communication of my personal data to public bodies and private companies for the purposes indicated in the information.

Name and Surname of the interested party (in capital letters) _____

Signature of the interested party _____

Date _____

ATTENTION: TO BE COMPLETED BY THE STUDY DOCTOR WHO OBTAINED CONSENT

I confirm that I have provided the patient with comprehensive explanations regarding the nature, purpose and duration of the study in question and that I have given him/her a copy of the information sheet and a dated and signed copy of the consent form.

I also confirm that I have provided the patient with information regarding the processing of personal and sensitive data and that I have received explicit written consent to the treatment.

Name of the doctor who explained and withdrew the consent:

Legible name and surname (or stamp):_____

Date (dd/mm/yyyy): |_|_|/|_|_|/|_|_|_|_| Signature: _____